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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,812	09/12/2000	Kenny L. Dang	ACS 54573 (23111)	8165

7590 02/25/2003

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/660,812	DANG ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 11-24, 26, 27 and 29-41 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11-13, 24, 30-32 and 41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-23, 26, 27, 29, 33-37 and 40 is/are allowed.
- 6) ☒ Claim(s) 1-4, 14-19 and 39 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 14 June 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 1/22/03 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/660,812 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 1/22/03 has been entered as Paper No.15. Changes to the title, specification and claims 1, 16, 20, 29 and 35 have been approved by the Examiner. New claim 41 has been added.
3. Newly submitted claim 41 is directed to an invention that is independent or distinct from the invention elected without traverse of Species 1 (Figures 4-6), there being no allowable generic claim. Therefore, claim 41 has been withdrawn from consideration. The claims currently pending are 1-5, 7-9, 11-24, 26, 27 and 29-41, of which claims 5, 11-13, 24, 30-32 and 41 are withdrawn from consideration. The claims being considered for further examination on the merits are 1-4, 7-9, 14-23, 26, 27, 29 and 33-40.

Claim Objections

- ✓ 4. Claims 19 and 38 are objected to because of the following informalities: "covered" on line 1 should be changed to --cover--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ✓ 6. Claim 14 recites the limitations "the stent distal end" and "the stent proximal end" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

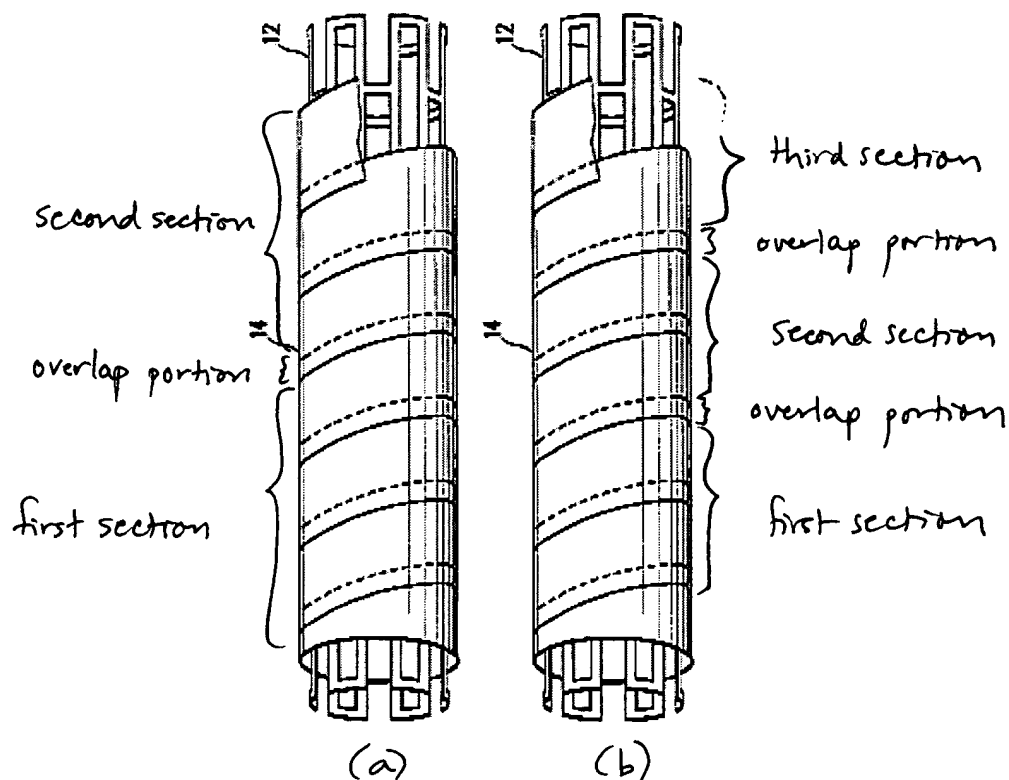
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 14, 17-19 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Freidberg (USPN 6,254,627).

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claim 1. See Figure 7(a) below and columns 5-6, lines 63-6 for an intravascular stent (12) and a cover material (14) surrounding the stent. The cover material has a first section and a second

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section forming an overlap portion. Applicant should note that use of the word “slidable” requires only that the first and second sections be *capable* of sliding with respect to each other along the longitudinal axis of the stent, not that portions are in fact sliding. Because the cover is wrapped around the stent such that it unwraps as the stent expands, it is evident that the sections forming the overlap portions are not attached or adhered together. This would clearly indicate that the first and second sections are indeed capable of sliding with respect to each other along the longitudinal axis of the stent, say for instance by pulling the sections apart in opposite directions along the longitudinal axis of the stent. See Figure 7(a) below.



Claims 2-4, see Figure 7(a) above and column 4, lines 5-8 for cover material distal and proximal ends being attached to the stent and the overlap portion being positioned there-between.

Claim 14, see column 4, lines 5-7 and columns 5-6, lines 63-6.

Claims 17-18, see Figure 7(b) above. The first two complete wraps is the first section, the next two complete wraps is the second section, and the next 1+ wrap is the third section. Between the sections is an overlap section, so that there is more than one overlap portion along the stent.

Claim 19, see column 4, lines 32-36 for cover material being within specified thickness range.

Claim 39, see column 4, lines 14-27.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg.

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claim 1, but is silent to the additional limitation of the cover material being attached to the stent by an adhesive, as required by claim 15. Freidberg discloses that the cover material (jacket) may be secured to the stent by any suitable means (column 4, lines 5-6) and securing the sides of the stent cover together is done by mechanical means that are old and well known in the art, including adhesive bonding (column 5, lines 35-37). Therefore, it would have been obvious to

one of ordinary skill in the art to use adhesive bonding to attach the cover material to the stent by an adhesive.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg in view of Sogard et al. (USPN 6,139,573).

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claim 1, but is silent to the cover material being made from ePTFE, PET or polyurethane, as required by claim 16. Sogard et al. discloses a conformal laminate stent device with a cover material made of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. It would have been obvious to one of ordinary skill in the art to make the biocompatible, non-thrombogenic expandable material of Freidberg of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. See column 2, lines 40-45.

Allowable Subject Matter

12. Claims 20-23, 26, 27, 29, 33-38 and 40 are allowed.

13. Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

14. Applicant's arguments filed 1/22/03 have been fully considered but they are not persuasive with respect to Freidberg '627. Applicant argues that Freidberg does not teach sliding along the longitudinal axis of the stent. As stated in the above rejection to claim 1, the word "slidable" requires only that the first and second sections be *capable* of sliding with respect to each other along the longitudinal axis of the stent, not that portions are in fact sliding.

15. In response to applicant's argument that the Freidberg reference does not disclose a first, second or third section and that it is improper to arbitrarily partition jacket 14 into sections when the patent is silent on the issue, Examiner refers applicant to the definition of "section". The word "section" is defined by Webster's II New Riverside University Dictionary to be: "a part or piece of something; portion". A section does not require that it be separate from the whole. Therefore, the first and second sections, without being given any other structural limitations defining the sections, can be broadly interpreted to be any arbitrary portions of the tubular cover that meet the limitation of the proximal end of the second section forming an overlap with the distal end of the first section. This is clearly shown by Freidberg, as indicated in Figure 7(a) above.

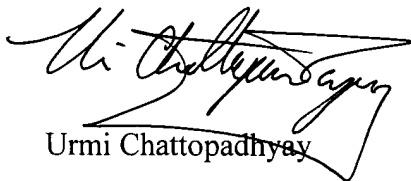
16. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

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In this case, the motivation to combine references is in the reference itself. It would have been obvious to one of ordinary skill in the art to make the biocompatible, non-thrombogenic expandable material of Freidberg of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. As stated above, this is clearly taught in column 2, lines 40-45 of Sogard et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner

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February 12, 2003